Washington State Department of Health

ELABORATIONS

News and Issues for Washington's Clinical Laboratories

Volume VIII Issue 1 January 2003

Conference Highlights: Patient Safety

by Leonard Kargacin

Michael Astion, MD, PhD, from the University of Washington, presented a session at the 9th Annual Clinical Laboratory Conference that was held on November 11, 2002, in Seattle. His presentation was titled "Laboratory Errors that Jeopardize Patient Safety." The following is a synopsis of this presentation.

An Institute of Medicine (IOM) report based on the Harvard Medical Practice Group Population Study of Medical Errors from the early 1990s retrospectively reviewed approximately 30,000 hospital records from New York from 1984. The study showed that 3.7% of hospital admissions had an adverse event. Of these, 48% of events were associated with operations; 8% with delayed diagnosis; 28% of events were due to negligence; 13.5% of events led to death; and 2.6% of events led to severe disability.

What is the lab's role in these adverse events? The knowledge of laboratory related adverse and potential adverse events comes from a few studies focusing on the rate of lab error, and the classification of lab error by phase of testing, the responsible party, etc. However, little is known about frequency of injury caused by lab error.

In order to obtain some data on laboratory errors, the University of Washington began a study called the UW Patient Safety Project. The purpose of the study was to decrease Adverse Events (AE) (an actual injury related to the patient's medical care) and Potential Adverse Events (PAE) (a near-miss such as a mislabeled specimen) related to lab services. Only a small fraction of PAE become AE; most are caught within the laboratory or by an alert physician, nurse, or even by the patient themselves (blood banking) either before the patient is involved or before treatment is started.

Classification System: One hundred twenty-nine incident reports from an academic medical center (not the University of Washington) were reviewed and classified regarding:

- adverse event and/or potential adverse event
- specific impact to patient, i.e., did a redraw of the specimen occur; was there a delay in receiving the test results; were incorrect test results sent to the provider; if an adverse event, describe; none of the above
- potential impact to patient (scored on a 1-5 scale; 1=unlikely to adversely affect health; 5=very likely to adversely affect health)
- responsibility for problem (inside or outside the lab, or both)

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Inside This Issue

Practice Guidelines

The following practice guidelines have been developed by the Clinical Laboratory Advisory Council. They can be accessed at the following website:
www.doh.wa.gov/lqa.htm

- Anemia
- ANA
- Bioterrorism Event Mgmt
- Bleeding Disorders
- Chlamydia
- Diabetes
- Group A Strep Pharyngitis
- Hepatitis
- HIV
- Intestinal Parasites
- Lipid Screening
- Point-of-Care Testing
- PSA
- Renal Disease
- STD
- Thyroid
- Tuberculosis
- Urinalysis
- Wellness

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- phase of lab testing (pre-analytic, analytic, post analytic)
- was the incident preventable? And if preventable, was it a "slip" or a "mistake".

"Mistakes" are errors due to lack of knowledge or poor judgment. Examples of mistakes might include mistaking yeasts for host cells on a Gram stain, inadequate staffing plan in processing, lab staff rejecting a specimen for malaria due to lack of knowledge about acceptable specimens, or a provider purposefully relabeling a mislabeled specimen in violation of policy.

"Slips" are errors in an automatic process. Examples of slips might include failure to enter information from the requisition into LIS, mislabeled specimens, experienced lab staff selecting the wrong specimen tube for a common test, specimen put in the incorrect transportation bin, choosing the wrong requisition for a STAT test.

The significance of mistakes vs. slips lies in the different responses to these two types of errors. To guard against mistakes you have to train people more or provide more supervision. To guard against slips, you might use checklists, automation, or other strategies for avoiding lapses in concentration.

On the 129 incident reports reviewed, 122 (95%) were potential adverse events only; 6 (5%) were adverse events only (almost all related to phlebotomy); 1 (1%) was an incident with both adverse and potential adverse events. The most common impact to patients was a delay in receiving test results.

Limitations of the current study: Incident reports tend to under-report AE and PAE and cannot be used to estimate the actual incident rates. They usually are missing important data (e.g., test results, patient care setting, outcomes), and they might not sample incidents randomly.

Summary: If laboratories would like to do a quality improvement (QI) project looking at patient safety in their institution, use the classification system listed above and enhance to include: specific tests and results; are requests STATs or routine; patient care setting (ICU, OR, ambulatory); patient history and diagnosis; patient outcomes. It is suggested that laboratories get beyond using incident reports only and use other error reporting options that already exist in the laboratory such as corrected report lists.

"ELABORATIONS" is a free monthly publication of the Washington State Department of Health (DOH) Public Health Laboratories (PHL) and Office of Laboratory Quality Assurance (LQA).

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NOTE: Letters to the editor may be published unless specified otherwise by the author.

Website addresses:
DOH home page: http://www.doh.wa.gov
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PHL home page:
http://www.doh.wa.gov/EHSPHL/PHL/default.htm

Conference Highlights: Six Sigma

by Leonard Kargacin

Rick Zimmer from Quest Diagnostics presented a session at the 9th Annual Clinical Laboratory Conference titled "Six Sigma: The Quality Improvement Breakthrough of the 21st Century." The following is a brief synopsis of this presentation.

The Six Sigma methodology is a quality improvement mechanism that has been used in industry since the 1970s. It has only recently been used in healthcare. The purpose is to drive quality in the workplace. When we talk about Six Sigma, we are talking about developing processes for making improvements that will result in only 3.4 errors or defects per million opportunities

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(99.9997% yield). Most companies are in the 2-4 Sigma level (308,538 errors and 6,210 errors per million opportunities respectively).

Any process can benefit from applying the Six Sigma methodologies: define; measure; analyze; improve; and control. It is a rigorous databased method for improvement. This system is a cultural change for the organization and must be supported from top management for it to work properly. In Six Sigma, everyone has responsibility; if you are not doing your job as well as you can, you are potentially contributing to the defects.

The goal in Six Sigma Quality is to meet the customer's definitions of "error-free" performance in everything that is done. Six Sigma requires every employee to take responsibility for their errors and to focus on eliminating the root causes. The processes are designed and executed to meet customer requirements completely and consistently.

Resources to learn more about Six Sigma:
Books:
- The Six Sigma Way: How GE, Motorola, and Other Top Companies are Honing their Performance. Peter Pande, et al.
- What is Six Sigma? Peter Pande, et al.
- Rath and Strong Six Sigma Pocket Guide. Rath and Strong.

Website: www.Isixsigma.com

Laboratory-Based Practice Guidelines

by Leonard Kargacin

A critical area of concern in the current cost-conscious healthcare environment is optimization of service delivery. Over-utilization of laboratory testing can lead to needless and costly treatment for the patient. Under-utilization can result in a misdiagnosis and delays in treatment. To address inappropriate or unnecessary use of laboratory testing services, the Clinical Laboratory Advisory Council decided to establish a process for developing practice guidelines for clinical laboratory testing. The guidelines are for educational purposes only.

The intent of the guidelines is to help laboratorians answer questions they may get from clinicians on appropriate test ordering. The guidelines will also be useful to clinicians as a review of a typical test-ordering pattern for patients. The guidelines are a compilation of existing data, not original work by the Council. For the format, the Council elected to summarize existing information into simple, easy-to-use flow charts. Once a test has been identified by the Council as a candidate for a guideline, a Council workgroup is formed to develop a proposed guideline. The draft guideline is reviewed by the entire Council, members of the state's laboratory community and appropriate medical professional societies. Comments from the reviewers are evaluated by the Council workgroup and incorporated into the final document. The finalized guideline is disseminated to all clinical laboratories and other interested parties through this newsletter.

FOR EDUCATIONAL PURPOSES ONLY

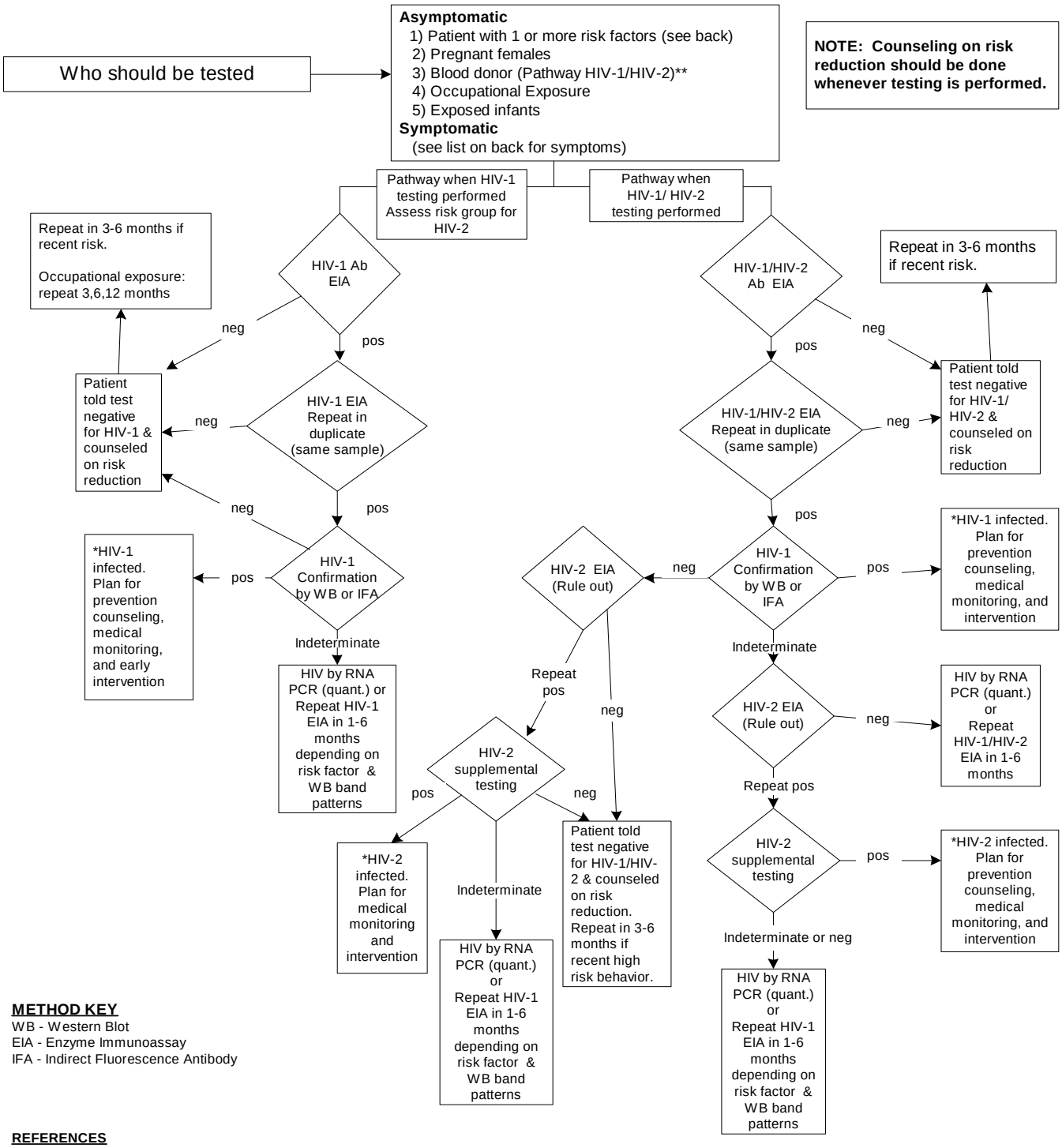
The guidelines should be used strictly as guidelines. The individual clinician is in the best position to determine which tests are most appropriate for a particular patient.

Guidelines developed by the Council that have been previously published in E**LAB**ORATIONS are listed in a box on the front page of this newsletter. This issue of E**LAB**ORATIONS contains the updated HIV Screening Guidelines.

HIV Screening Guidelines

Washington State Clinical Laboratory Advisory Council
Orginally published: July 1997
Updated: October 2002

FOR EDUCATIONAL PURPOSES ONLY
The individual clinician is in the best position to determine which tests are most appropriate for a particular patient.



METHOD KEY
WB - Western Blot
EIA - Enzyme Immunoassay
IFA - Indirect Fluorescence Antibody

REFERENCES

1) MMWR Vol. 38/No. S-7, page 4. Vol. 41/No. RR-12, page 7.
2) KNOW, AIDS Prevention Curriculum, Washington State Office on HIV/AIDS.
3) HIV Counseling and Testing WSDH HIV/AIDS Education and Prevention. Adapted from Group Health Cooperative Pamphlet 4/97.
4) Indeterminate HIV-1 Western Blots: Implications and considerations for widespread HIV testing. C. Celum, MD, MPH, R. Coombs, MD, PhD. Journal of General Internal Medicine. Vol. 7 (Nov/Dec 1992), pp. 640-645.

***In infants, detection of Ab soon after birth may indicate either infection or presence of maternal HIV Ab. Seropositive infants require further follow-up.

**For blood donors testing negative, it is not required to notify the donor of the result, counsel on risk reduction, or repeat testing in 3-6 mos.

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RISK FACTORS

HIV testing is recommended for persons (or partners of persons) who currently or in the past have had a history of the following risks:

- unprotected sexual intercourse (anal, vaginal or oral);
- injection drug use, especially sharing needles and/or other equipment;
- sex for money or drugs;
- blood transfusions, between 1977-1985;
- sexually transmitted disease (STD);
- is a child of a HIV-infected mother; and,
- sex/shared injection drug equipment with someone who is known to be HIV infected.

HIV testing is also recommended for any person who:

- is contemplating pregnancy or currently pregnant;
- has had an Occupational Exposure (OE); and,
- has received medical treatment in areas of the world where non-sterile techniques/equipment or untested blood may have been used.

CLASSIFICATION SYSTEM FOR HIV INFECTION

CD4 Cell Categories	Clinical Categories (see notes below for explanation of Categories A, B, and C)		
	A Asymptomatic, or PGL*, or Acute HIV Infection	B** Symptomatic (not A or C)	**C***** AIDS-Indicator Condition
1 > 500/mm^3 (>29%)	**A1**	**B1**	**C1**
2 200-499/mm^3 (14-28%)	**A2**	**B2**	**C2**
3 < 200/mm^{3***} (<14%)	**A3**	**B3**	**C3**

* Persistent Generalized Lymphadenopathy (swollen lymph nodes)
** Symptoms of chronic HIV, not AIDS-defining. See below.
*** All people in categories A3, B3, and C 1-3 are defined as having AIDS

A INITIAL SYMPTOMS AND STAGES OF HIV INFECTION

- Viral transmission - incubation period of 2-3 weeks followed by Acute Retroviral Syndrome, lasting 2-3 weeks.
- Acute HIV infection usually presents as flu-like illness, e.g. fever, swollen lymph nodes, sore throat, rash, body aches. Also can be asymptomatic. CD4 cell counts drop precipitously and HIV viral RNA is very high.
- Symptomatic recovery - viral RNA declines and CD4 counts climb to normal. HIV infection is now widespread. HIV antibody tests are positive (seroconversion) after 14 days in most people, virtually all by 6 months. Some people develop Persistent Generalized Lymphadenopathy (PGL).
- Asymptomatic, chronic HIV infection phase affecting most people lasting an average of 8 yrs. The virus continues to replicate actively, CD4 counts decline and HIV RNA levels gradually increase.

B SYMPTOMS OF CHRONIC HIV INFECTION (NOT ASYMPTOMATIC, PGL, OR ACUTE HIV INFECTION; AND NOT AIDS-INDICATOR CONDITIONS)

Symptomatic conditions not included in Category C that are
a) attributed to HIV infection or indicative of a defect in cell-mediated immunity, or
b) considered to have a clinical course or management complicated by HIV infection.
Examples include: oral thrush, persistent vaginal candidiasis, bacillary angiomatosis, cervical dysplasia or carcinoma in situ, constitutional symptoms such as severe fatigue, persistent fever or diarrhea, oral hairy leukoplakia, herpes zoster involving two episodes or muti-dermatomal, idiopathic thrombocytopenic purpura (ITP), listeriosis, pelvic inflammatory disease (PID) and peripheral neuropathy.

C AIDS-INDICATOR CONDITIONS

Late-stage disease is characterized by opportunistic infections, selected malignancies, wasting and neurologic complications. Untreated, the median survival after an AIDS-defining complication is 1.3 years. Conditions present at time of AIDS diagnosis in decreasing frequency:

- Pneumocystis carinii pneumonia (38%)
- HIV-associated wasting (18%)
- Candidiasis of esophagus, trachea, bronchi or lungs (16%),
- Mycobacterium tuberculosis, pulmonary (7%), extra pulmonary (2%)
- CMV of eye or any organ other than liver, spleen or lymph nodes (7%)
- Kaposi's sarcoma (7%)
- Cryptococcosis, extrapulmonary (5%)
- Herpes simplex with ulcer >1 month or bronchitis, pneumonitis, esophagitis (5%)
- HIV-associated dementia (5%)
- Mycobacterim avium, disseminated (5%)
- Pneumonia, recurrent-bacterial (5%)
- Toxoplasmosis of internal organ (4%)
- Lymphoma, Burkitt's (0.7%), immunoblastic (2.3%), primary CNS (0.7%)
- Cryptosporidiosis with diarrhea >1 month (1.3%)
- Progressive Multifocal Leukoencephalopathy (1%)
- Histoplasmosis, extra pulmonary (0.9%)
- Cervical cancer, invasive (0.6%)
- Coccidioidomycosis, intrapulmonary (0.3%)
- Salmonella septicemia (nontyphoid), recurrent (0.3%)
- Isosporiasis with diarrhea >1 month.

Waived Testing Helpful Hints

In the last issue, we discussed Good Laboratory Practice (GLP) #3: Check kit expiration date. Here is GLP #4: Know the package insert.

√ Keep the manufacturer's package insert for the test in use; be sure it is available to the testing personnel.

√ Follow the most current package insert (check the last page for the date); do not use old package inserts.

√ Become familiar with the package insert before testing. Focus on the following parts of a package insert:

- Intended Use/Summary
- Specimen Collection and Preparation
- Storage Requirements or Stability
- Quality Control
- Procedure
- Results/Interpretation

NOTE: Check this spot in future editions of Elaborations for more helpful hints with waived testing.

Calendar of Events

PHL Training Classes:

Shipping & Handling Biohazardous Materials

February 12	Shoreline
February 13	Spokane

Parasitology Part II: Protozoans

February 26-27	Shoreline

Blood Cell Morphology

March 12	Shoreline
March 13	Shoreline

CDC Quality Institue Conference 2003
(www.phppo.cdc.gov/mlp/qiconference/default.asp)
April 13-15 Atlanta, GA

WSSCLS/NWSSAMT Spring Meeting
April 24-26 Pasco

Northwest Medical Laboratory Symposium
October 22-25 Olympia

10th Annual Clinical Laboratory Conference
November 10 Seattle

Contact information for the events listed above can be found on page 2. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 2. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.

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